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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,447	02/06/2002	Kurt R. Gehlsen	MAXIM.073DV1C1	1030

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EXAMINER

BERKO, RETFORD O

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/068,447

Applicant(s)

GEHLSSEN, KURT R.

Examiner

Retford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 26-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other:

*Acknowledgement: Receipt of Information Disclosure Statement filed May 23, 2002 is acknowledged.*

**Claim Rejections - 35 USC § 102**

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claim 26-41 are rejected under 35 U.S.C. 102 (b) as anticipated by Hellstrand et al (WO 97/42968).

According to applicant's 26 and 34, applicant's invention is a method of making a composition with a carrier for dermal application: the composition comprises of a compound that inhibits enzymic release of reactive oxygen metabolites (or species). The compound can be histamine or its salt, serotonin or pro-drug, retinoic acid or derivative or allergens at concentrations effective for treatment of reactive oxygen metabolite- mediated skin damage or disorder resulting from viral or bacterial infections, mucositis induced by radiotherapy, thermal burns, etc.

3. As in applicant's claims 26, 34 the patent issued to Hellstrand (Patent WO'WO '968) teaches methods for obtaining and using histamine-inducing compound for preparation of medicament. WO'968 teaches that the composition containing compounds such as histamine, histamine phosphate, esters, serotonin,, IL-3, and allergens can be applied to patients through transdermal formulations (abstract, page 11, lin 5,page 12, lin 1-5, page 13, lin 15-25, and page 20, lin 15-25).

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4. As in applicant's claim 27, 36 the composition boots circulating levels of endogenous histamine (page 15, lin 12, page 16, lin 25-30 and page 20, lin 35).

5. WO '801 teaches that the composition can be made in a gel formulation (page 20, lin 18): one can envisage the gel formulation in the form of shampoo (as claimed by applicant in claim 30).

6. WO '968 teaches that the compounds—IL-3, retinoids and ingestible allergens-- as in applicant's claim 37 promote the release of histamine from endogenous stores (page 20, lin 5-25).

7. In claims 38-41, applicant claims that the composition in various formulations comprise colorants, dye, fragrance or moisturizers. WO '968 teaches a wide variety of routes of administration and carriers for the composition, including powders, dispersions, glycerol, polyethylene glycol, mixtures and oils. It is conceivable that such variety of formulations and carriers can be made into cosmetic powders, moisturizers, etc. through mere additive or subtractive effects to achieve desired formulation. Such actions on the part of the applicant do not necessarily lend inventive support to applicant's claims.

8. Claim 26, 27, 29, 34, 36 are rejected under 35 U.S.C. 102 (b) as anticipated by Bruce et al (WO 95/23601).

9. As in applicant's claims 26, WO '601 teaches method and composition for topical treatment of skin damage resulting from viral, bacterial infections, thermal burn and sunburn. The active ingredient in the composition is histamine phosphate—imidazole-4-ethamine phosphate (IEP) (abstract, page 2, lin 1; page 71, lin 5-20). WO '601 teaches that the IEP in its precursor form (pro-drug) can be used for preparation of the active drug for use in the

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composition (page 69, lin 30 continuing to page 70). Because it is widely known in the art that histamine, histamine phosphate and other analogues are compounds with anti-apoptotic activity useful as antioxidants for prevention of diseases due to ability in removing cellular free radicals (ROM scavenger action), it is implicit that the disclosure in WO '601 teaches that the composition using histamine phosphate as ingredient meets the limitations in applicant's claims 26 and 27.

10. As in applicant's claims 26, 29 and 34, WO '601 teaches that histamine phosphate is used for topical treatment of sunburn as well as other skin conditions (page 71, lin 5). WO '601 teaches examples wherein histamine phosphate preparation is effective for skin damage such as blisters or cold sores. Thus the formulation can be used as lipstick or other lip preparations such as gels.

### **Claim Rejections - 35 USC § 103**

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 28, 29, 30, 34-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce et al (WO '601) in view of Bathurst et al (US 6, 004, 579).

13. WO '601 teaches method and composition for topical treatment of skin damage resulting from viral, bacterial infections, thermal burn and sunburn. The active ingredient in the composition is histamine phosphate—imidazole-4-ethamine phosphate (IEP) (abstract, page 2, lin 1; page 71, lin 5-20). WO '601 teaches that the composition comprising histamine phosphate as ingredient can be described in various modification without departing from the true spirit and

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scope of the invention (i.e. treatment of damaged tissue). WO '601 does not teach that the histamine phosphate composition can be made as a lipstick, shampoo, spray or mouthwash formulation.

14. Bathurst et al (Patent '579) teaches composition that inhibits apoptosis termed ROM, comprising essentially of phospholipids (named Elirex <sup>TM</sup>, col 2, lin 65, col 4, lin 5, col 17, lin 15) and that the composition can be applied directly to the skin or incorporated into a transdermal patch device (col 11, lin 40-50). Patent '579 also teaches that the composition is for treating various dermatological conditions (col 14, lin 55), that the composition can be formulated into various topically acceptable liquids, creams, lotions, gels etc; and that additional ingredients conventionally used in cosmetic art could be included; including vitamin A.

15. One of ordinary skill would have been motivated to make a composition for topical treatment of skin conditions mediated through ROM, such comprising histamine or histamine phosphate and include other ingredients such as retinoic acid or its derivatives in many formulations (e.g. shampoo, lotions, lipstick, spray). One of ordinary skill would have expected to obtain an effective topical treatment of skin damage brought on through viral or bacterial infection and sunburn without being limited to only one formulation as a choice thereby increasing market acceptability. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Retford Berko whose telephone number is 703-305-4442. The examiner can normally be reached on M-F at 8:00 a.m.-5:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9903 for regular communications and 703-746-9903 for After Final communications.

An inquiry of a general nature or relating to the status of this communication or proceeding should be directed to the receptionist whose telephone number is 703-308-1243.

  
**THURMAN K. PAGE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**